
शिशुओं के लिए स्किन पाउडर

(तीसरा पुनरीक्षण)

Skin Powder for Infants — Specification

(*Third Revision*)

ICS 71.100.70

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FOREWORD

This Indian Standard (Third Revision) was adopted by the Bureau of Indian Standards after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

This standard was originally published in 1969 and revised in 1978 and 2004, respectively. In second revision, limiting requirement of microbial content was prescribed as skin powders for infants should not cause any bacteriological and fungal contamination. This possibility may be obviated by, for instance, a process of sterilization. The marking requirements of best use before, list of key ingredients on containers and ECO Mark certification were also incorporated in this revision. Since starch can also be used as a base ingredient for skin powder for infants, three different types depending upon the base ingredient namely, talc, starch or both in combination were introduced in this standard through Amendment 3.

As Amendment 3 to the second revision (2004) brought major changes to the standard, the Sectional Committee decided to revise the standard by incorporating all the 3 amendments. In this revision, following major changes have been made:

- a) all three amendments to the second revision (2004) have been incorporated,
- b) requirements of '*Matter insoluble in boiling water*' and '*Moisture and volatile matter*' for Type 3 Skin powder for infants has been incorporated [Table 1, SI No. (i) and (iii)],
- c) the limiting requirement of mercury (1 ppm) has been incorporated [Table 1, SI No. (vii)],
- d) an alternate test method for determination of heavy metals and Arsenic (AAS method, IS 16913) has been incorporated [Table 1, SI No. (v) and (vi)],
- e) the microbial limits have been modified [Table 1, SI No. (ix)], and
- f) the marking clause has been harmonized with Rule 148 of the Drugs and Cosmetics Rules, 1945.

This standard covers the cosmetic products commonly known as baby powders in trade. These powders are intended to make the infant feel more comfortable and to help prevent skin rashes that arise from or are aggravated by excess moisture. In composition, skin powders for infants do not differ greatly from those intended for adults. One obvious difference is that the infant powders are usually only lightly perfumed or not perfumed at all. The principle followed by many manufacturers is to keep the formula as simple as possible. This reduces the risk of sensitization and irritation. For this reason, there are often as few as three or four ingredients in these powders. Stearates, colloidal clay, starch and/or talc are the common ingredients. Another significant difference is that these powders are free from boric acid.

No stipulations have been made in this standard regarding the composition of skin powders. However, it is necessary that the raw materials used are such that in the concentrations in which they would be present in the finished skin powder, after interaction with other raw materials used in the formulation, they are free from any harmful effects. It shall be the responsibility of the manufacturers of skin powder for infants to satisfy themselves of the dermatological safety of their formulation before releasing the product for sale.

A scheme for labeling environment friendly product as known as ECO-Mark was introduced at the instance of the Ministry of Environment and Forests and Climate Change (MEF&CC), Government of India. The ECO-Mark is being administered by the Bureau of Indian Standards (BIS) under the *Bureau of Indian Standards Act, 1986* as per the Resolution No. 71 dated 21 February 1991 and No. 768 dated 24 August 1992 published in the Gazette of the Government of India. For a product to be eligible for marking with ECO logo it shall also carry the Standard Mark of BIS besides meeting additional environment friendly requirements. For this purpose, the Standard Mark of BIS would be a single mark being a combination of the BIS monogram and the ECO logo. Requirements for ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also. The additional requirements for ECO-Mark are given at 5.

The composition of the Committee responsible for formulation of this standard is given at Annex J.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

SKIN POWDER FOR INFANTS — SPECIFICATION

(Third Revision)

1 SCOPE

1.1 This draft standard prescribes the requirements and methods of sampling and test for skin powder for infants below three years age.

1.2 This standard does not cover skin powder for general use, for which a separate Indian Standard, IS 3959 : 2004 ‘Skin powder — Specification (*second revision*)’ has been published.

2 REFERENCES

The following standards are necessary adjuncts to this standard. The standards contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

<i>IS No.</i>	<i>Title</i>
2088 : 1983	Methods for determination of arsenic (<i>second revision</i>)
3958 : 1984	Methods of sampling cosmetics (<i>first revision</i>)
4011 : 2018	Methods of test for safety evaluation of cosmetics (<i>third revision</i>)
4707	Classification of cosmetic raw materials and adjuncts
(Part 1) : 2017	Colourants (<i>third revision</i>)
(Part 2) : 2017	List of raw materials generally not recognized as safe for use in cosmetics (<i>fourth revision</i>)
14648 : 2011	Microbiological examination of cosmetics and cosmetic raw materials — Methods of test (<i>second Revision</i>)

3 TYPES

3.1 Depending on the base ingredient(s), there shall be three types of skin powder for infants, namely:

- a) **Type 1**, with talc as base ingredient (90 percent, *Minimum*);
- b) **Type 2**, with starch as base ingredient (90 percent, *Minimum*); and
- c) **Type 3**, with talc and starch as base ingredients, in any combination (total 90 percent, *Minimum*).

4 REQUIREMENTS

4.1 Skin powder for infants shall consist principally of a finely-powdered free flowing absorbent innocuous material such as natural talc and/or starch and may contain mild perfume, as well as other ingredients consistent with the accepted practice in the cosmetic industry.

4.2 The powder shall essentially be free from colouring matter. It may be buffered to control pH. It shall be free from boric acid when tested by the method prescribed in Annex A.

4.3 Unless specified otherwise, all the raw materials used in the manufacture of skin powder for infants shall conform to the requirements prescribed in the relevant Indian Standards where these exist.

4.4 The ingredients used, if any, shall comply with the provisions of IS 4707 (Part 2) and latest International Fragrance Association (IFRA) standards for safe use of fragrance materials.

4.5 For safety evaluation of novel ingredients used in the formation of a skin powder for infants, the skin powder for infants shall comply to IS 4011.

4.6 Skin powder for infants shall also comply with the requirements given in Table 1 when tested as prescribed in col 6 of the Table 1.

5 ADDITIONAL REQUIREMENTS FOR ECO MARK (OPTIONAL)

5.1 Requirements for quality, safety and performance prescribed under **5.1.1** to **5.1.4**.

5.1.1 All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2). The product shall also meet specific requirements as given in the standard.

5.1.2 The product package shall display a list of key ingredients in descending order of quantity present.

5.1.3 The product shall not be manufactured from any carcinogenic ingredients.

5.1.4 The manufacturer shall produce to BIS environmental consent clearance from the concerned State Pollution Control Board as per the provisions of the *Water (Prevention and Control of Pollution) Cess Act, 1977* and the *Air (Prevention and Control Pollution) Act, 1981* along with the authorization, if required under the *Environment (Protection) Act, 1986* and the Rules made there under, while applying for ECO Mark. Additionally, provisions of the *Drugs and Cosmetics Act, 1940* and the Rules thereunder shall also be complied with.

5.2 Specific Requirements

5.2.1 Product shall be dermatologically safe when tested as per IS 4011.

5.2.2 Heavy metals calculated as lead (Pb) and arsenic (as As_2O_3) shall not exceed 20 and 2 ppm, respectively when tested by the respective method prescribed in Indian Standards.

5.2.3 For ECO Mark the product package shall be packed in such packages which shall be recyclable or biodegradable.

6 PACKING AND MARKING

6.1 Packing

The material shall be packed in suitable well-closed containers.

6.2 Marking

The labelling and marking of skin powder for infants shall comply with the provisions of the Drugs and Cosmetic Rules, the Legal Metrology Rules and any other relevant statutory requirement. In addition, the packaging shall be legibly marked with the following information:

- a) The wording "Skin powder for infants" or equivalent
- b) Type of Skin powder for infants (Type 1 or Type 2 or Type 3)
- c) Percent composition of talc and starch to be declared on label for Type 3 Skin powder for infants.

6.3 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the standard mark.

6.4 If the product is covered under ECO Mark (optional), it shall be suitably marked with ECO Mark logo besides Standard Mark. The label may clearly specify that ECO Mark is applicable to the contents or the package or both, as case may be. If the product package is not separately covered under ECO Mark scheme, it shall be clearly mentioned on the product that ECO Mark label is applicable to contents only.

7 SAMPLING

7.1 Representative samples of the material shall be drawn as prescribed in IS 3958.

7.2 Tests for all the characteristics shall be carried out on the composite sample as per methods referred under col 6 of Table 1.

7.3 The material shall be taken to have conformed to the standard if the composite samples passes all the tests.

8 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water [see IS 1070 : 1992 'Reagent grade water (third revision)'] shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

Table 1 Requirements for Skin Powder for Infants
(Clause 4.6)

Sl No.	Characteristics	Requirement			Method of Test, Ref to Annex/IS
		Type 1 (3)	Type 2 (4)	Type 3 (5)	
(1)	(2)	(3)	(4)	(5)	(6)
i)	Matter insoluble in boiling water, percent by mass, <i>Min</i>	90.0	—	(Talc content × 0.9)	B
ii)	Fineness				C
	Residue on 75-micron IS Sieve, percent by mass, <i>Max</i>	2.0	2.0	2.0	
	Residue on 150-micron IS Sieve, percent by mass, <i>Max</i>	0.5	0.5	0.5	
iii)	Moisture and volatile matter, percent by mass, <i>Max</i>	2.0	15.0	(Talc content × 0.02) + [(100 – Talc content) × 0.15] Or (Starch content × 0.15) + [(100 – starch content) × 0.02]	D
iv)	pH of aqueous suspension	5.5 to 8.0	5.5 to 8.0	5.5 to 8.0	E
v)	Heavy metals (as Pb) ¹⁾ , parts per million, <i>Max</i>	20	20	20	F/IS 16913
vi)	Arsenic (as As ₂ O ₃) ¹⁾ , parts per million, <i>Max</i>	2	2	2	G/IS 16913
vii)	Mercury, parts per million, <i>Max</i>	1	1	1	IS 16913
viii)	Loss on ignition, percent	9 (<i>Max</i>)	98 (<i>Min</i>)	—	H
ix)	Microbial limits				
a)	Total microbial count, CFU/g, <i>Max</i>	100	100	100	IS 14648
b)	Yeast and mould count, CFU/g, <i>Max</i>	100	100	100	IS 14648
c)	Escherichia coli, per gram	Absent	Absent	Absent	IS 14648
d)	Pseudomonas aeruginosa, per gram	Absent	Absent	Absent	IS 14648
e)	Staphylococcus aureus, per gram	Absent	Absent	Absent	IS 14648
f)	Candida albicans, per gram	Absent	Absent	Absent	IS 14648

¹⁾ In case of any dispute with respect heavy metal and arsenic content, methods of test prescribed at Annex :F and G, respectively shall be the reference method.

ANNEX A
(Clause 4.2)

TEST FOR FREEDOM FROM BORIC ACID

A-1 REAGENTS

A-1.1 Concentrated Sulphuric Acid — [see IS 266 : 1993 ‘Sulphuric acid — Specification (*third revision*)’].

A-1.2 Rectified Spirit — [see IS 323 : 2009 ‘Rectified spirit for industrial use — specification (*second revision*)’].

A-2 PROCEDURE

Weigh about 1 g of the material in a porcelain or China dish. Add about 2 ml of concentrated sulphuric acid and stir thoroughly with a glass rod. Then add about 5 ml of rectified spirit and again stir thoroughly. Ignite and observe the appearance of the flame.

A-2.1 The material shall be considered to be free from boric acid if the flame does not have a green outer edge.

ANNEX B

[*Table 1, Sl No. (i)*]

DETERMINATION OF MATTER INSOLUBLE IN BOILING WATER**B-1 REAGENT**

B-1.1 Rectified Spirit — [see IS 323 : 2009 ‘Rectified spirit for industrial use — Specification (*second revision*)’].

B-2 PROCEDURE

Weigh accurately about 1g of the material and transfer to a 500 ml beaker. If necessary, wet the material with a little rectified spirit. Add to the beaker about 200 ml of water and boil. Allow to settle and filter the supernatant liquid through a Gooch crucible. Wash the residue in

the beaker with water and transfer completely to the filter. Dry the residue in the crucible at 105 ± 2 °C to constant mass.

B-3 CALCULATION

Matter insoluble in boiling water, percent by mass

$$= \frac{100 \times M_1}{M}$$

where

M_1 = mass in g, of the residue; and

M = mass in g, of the material taken for the test.

ANNEX C

[*Table 1, Sl No. (ii)*]

DETERMINATION OF FINENESS**C-1 REAGENT**

C-1.1 Denatured Spirit — Filtered.

C-2 PROCEDURE**C-2.1 For Type 1**

Place about 10 g of the material, accurately weighed, in the specified IS Sieve [see IS 460 (Part 1) : 1985 Specification for test sieves: Part 1 Wire cloth test

sieves (*third revision*)] and wash by means of a slow stream of running tap water and finally with fine stream from a wash bottle until as much material as would pass through the sieve has passed. In case the material is not easily wetted by water, the washing could be started with a slow stream of filtered denatured spirit. Let the water drain from the sieve and then dry the sieve containing the residue on a steam bath or oven. Transfer the residue onto a tared watch glass carefully and dry it to constant mass at 105 ± 2 °C.

C-2.2 For Type 2 and Type 3

Place about 10 g of the material, in the specified IS Sieve [see IS 460 (Part 1) : 1985 specification for test sieves: Part 1 Wire cloth test sieves (*third revision*)]. After complete transferring of weighed quantity of material on sieve initially gently shake sieve in horizontal direction. Try to pass maximum possible quantity of the weighed material through sieve by shaking sieve in horizontal direction. Now use clean dry camel hair soft brush to remove any clogging of sieve or break of lump due to material. With the help of brush try to pass material through sieve by applying gentle pressure on material. After confirming that no more material is passing through the sieve then residue left on the sieve

shall be transfer on tarred weighed butter paper. Note the weight of residue of material left on sieve.

C-3 CALCULATION

Material retained on the specified sieve, percent by mass

$$\frac{100 \times M_1}{M}$$

where

M_1 = mass in g, of the residue retained on the specified sieve, and

M = mass in g, of the material taken for the test.

ANNEX D

[*Table 1, Sl No. (iii)*]

DETERMINATION OF MOISTURE AND VOLATILE MATTER**D-1 PROCEDURE**

Weigh accurately about 5 g of the material in a porcelain or glass dish, about and about 6 to 8 cm in diameter and about 2 to 4 cm in depth. Dry in an air oven at a temperature of 105 ± 2 °C to constant mass (within ± 5 mg)

D-2 CALCULATION

Moisture and volatile matter, percent by mass

$$\frac{100 \times M_1}{M}$$

where

M_1 = loss in mass in g, on drying; and

M = mass in g, of the material taken for the test.

ANNEX E

[*Table 1, Sl No. (iv)*]

DETERMINATION OF pH OF AQUEOUS SUSPENSION**E-1 PROCEDURE**

Take 10 g of the material in a 150 ml beaker and add 90 ml of freshly boiled and cooled water or purified water. Stir well to make a thorough suspension.

Determine the pH of the suspension at a temperature of 25 ± 1 °C, using a pH meter within 5 min of making the suspension. In case of a material which does not wet, the pH shall be determined on the filtrate.

ANNEX F

[*Table 1, Sl No. (v)*]

TEST FOR HEAVY METALS

F-1 OUTLINE OF THE METHOD

The colour produced with hydrogen sulphide solution is matched against that obtained with standard lead solution.

F-2 APPARATUS

F-2.1 Nessler Cylinders — 50 ml capacity.

F-3 REAGENTS

F-3.1 Dilute Hydrochloric Acid — Approximately 5 N.

F-3.2 Dilute Acetic Acid — Approximately 1 N.

F-3.3 Dilute Ammonium Hydroxide — Approximately 5 N.

F-3.4 Hydrogen Sulphide Solution — Standard.

F-3.5 Standard Lead Solution — Dissolve 1.600 g of lead nitrate in water and make up the solution to 1 000 ml. Pipette out 10 ml of the solution and dilute again to 1 000 ml with water. One millilitre of this solution contain 0.01 mg of lead (as Pb).

F-4 PROCEDURE

Weigh about 2.000 g of material in a crucible and heat on a hot plate and then in a muffle furnace to ignite it at 600 °C to constant mass. Add 3 ml of dilute hydrochloric acid, warm (wait till no more dissolution occurs) and make up the volume to 100 ml. Filter the solution. Transfer 25 ml of the filtrate into a Nessler's cylinder. In the second Nessler's cylinder, add 2 ml of dilute acetic acid, 1.0 ml of standard lead solution and make up the volume with water to 25 ml.

Add 10 ml of hydrogen sulphide solution to each Nessler cylinder and make up the volume with water to 50 ml. Mix and allow to stand for 10 min. Compare the colour produced in the two Nessler's cylinders. Blank determination without samples are recommended to avoid errors arising out of reagents.

F-5 RESULTS

The sample may be taken to have passed the test, if the colour developed in the sample solution is less than that of standard solution.

ANNEX G

[*Table 1, Sl No. (vi)*]

DETERMINATION OF ARSENIC

G-1 OUTLINE OF THE METHOD

Arsenic present in a solution of the material is reduced to arsine, which is made to react with mercuric bromide paper. The stain produced is compared with a standard stain.

G-2 REAGENTS

G-2.1 Mixed Acid — Dilute one volume of concentrated sulphuric acid with four volumes of water. Add 10 g of sodium chloride for each 100 ml of the solution.

G-2.2 Ferric Ammonium Sulphate Solution — Dissolve 64 g of ferric ammonium sulphate in water containing 10 ml of mixed acid and make up to one litre.

G-2.3 Concentrated Hydrochloric Acid — [see IS 265 : 1993 'Hydrochloric acid — Specification (fourth revision)']

G-2.4 Stannous Chloride Solution — Dissolve 80 g of stannous chloride ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

G-3 PROCEDURE

Carry out the test as prescribed in IS 2088, adding into the Gutzeit bottle, 2 ml of Ferric ammonium sulphate solution, 0.5 ml of stannous chloride solution and 25 ml of sample solution as prepared in F-4.

For comparison, prepare a stain using 0.001 mg of arsenic trioxide.

ANNEX H[*Table 1, Sl No. (ix)*]**DETERMINATION OF LOSS ON IGNITION****H-1 PROCEDURE**

Weigh accurately about 4 g of the material in a tared crucible and ignite at red heat to constant mass. Cool in a desiccator and weigh.

$$\frac{100 \times (M - m)}{M}$$

m = mass in g, of the ignited material; and

M = mass in g, of the material taken for the test.

H-2 CALCULATION

Loss on ignition, percent by mass.

ANNEX J

(*Foreword*)

COMMITTEE COMPOSITION

Cosmetics Sectional Committee, PCD 19

<i>Organization</i>	<i>Representative(s)</i>
Drugs Controller General (INDIA), Delhi	DR V. G. SOMANI (Chairman)
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Food and Drugs Control Administration Gujarat, Gandhinagar	DR H. G. KOSHIA SHRI V. R. SHAH (<i>Alternate</i>)
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Food and Drugs Administration Maharashtra, Mumbai	SHRI O. S. SADHWANI
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Member Secretary

SHRIMATI D. UMA
SCIENTIST 'D' (PCD), BIS

Composition of Skincare Products subcommittee, PCD 19:3

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In Personal Capacity	Ms RENUKA THERGAONKAR

Bureau of Indian Standards

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

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